

UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Vignina 22313-1450 www.nspto.gov

APPLICATION NO.	TION NO. FILING DATE		FIRST NAMED INVENTOR Radmila Micanovic	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,019		09/07/2001		X-13161	9268
25885	7590	09/29/2003			
ELI LILLY AND COMPANY				EXAMINER	
PATENT DI P.O. BOX 6			O HARA, EILEEN B		
INDIANAPOLIS, IN 46206-6288					
	02.0,	10, 111 10200 0200		ART UNIT	PAPER NUMBER
				1646	
				DATE MAILED: 09/29/2003	
					φ

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
-	09/936,019	MICANOVIC ET A	MICANOVIC ET AL.				
Office Action Summary	Examin r	Art Unit					
Office Action Gamma.y	Eileen O'Hara	1646					
The MAILING DATE of this communication a		1 1	dress				
Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REF THE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a r - If NO period for reply is specified above, the maximum statutory peri - Failure to reply within the set or extended period for reply will, by stat - Any reply received by the Office later than three months after the ma earned patent term adjustment. See 37 CFR 1.704(b). Status	N. 1.136(a). In no event, however, ma reply within the statutory minimum of od will apply and will expire SIX (6) it	y a reply be timely filed thirty (30) days will be considered timel MONTHS from the mailing date of this of ARANDONED (35 U.S.C. § 133).	y. ommunication.				
1) Responsive to communication(s) filed on _	·						
	This action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims							
4) Claim(s) <u>1-10,12-16 and 21</u> is/are pending	in the application.						
4a) Of the above claim(s) is/are without	drawn from consideration.	•					
5) Claim(s) is/are allowed.							
6)☐ Claim(s) is/are rejected.							
7) ☐ Claim(s) is/are objected to.							
8) Claim(s) 1-10, 12-16 and 21 are subject to restriction and/or election requirement.							
Application Papers							
9) The specification is objected to by the Examiner.							
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for for	reign priority under 35 U.S	S.C. § 119(a)-(d) or (f).					
a) ☐ All b) ☐ Some * c) ☐ None of:							
1. ☐ Certified copies of the priority docum	nents have been received	l.					
2. Certified copies of the priority docum	nents have been received	I in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-94) 3) Information Disclosure Statement(s) (PTO-1449) Paper No.	8) 5) Not	erview Summary (PTO-413) Paper lice of Informal Patent Application (ler:	No(s) PTO-152)				

Application/Control Number: 09/936,019

Art Unit: 1646

DETAILED ACTION

Election/Restrictions

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: FLINT analogs having specific amino acid changes in the protein of SEQ ID NO: 1. Given the immense number of possible species, examples of three species are given below.

For example, one FLINT analog would be with Arg at position 218 replaced by Gln.

Another FLINT analog would be with Arg at position 218 replaced by Ser.

Another FLINT analog would be with Thr at position 216 replaced by Pro, and Arg at position 218 replaced by Gln.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

Application/Control Number: 09/936,019

Art Unit: 1646

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: No claim is generic.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: although the Flint analogs all require a change in amino acid position 218 relative to the prior art protein to make them resistant to proteolysis, depending upon what that amino acid change is, the resulting proteins have different biological activities (see page 61). Also, additional changes at the other amino acids confer different biological activities upon the proteins (see biological activities of some analogs on page 61), and therefore the amino acid change at position 218 does not constitute a unifying technical feature for all the different claimed protein variants.

A telephone call was made to Thomas Webster on Sept. 24, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Application/Control Number: 09/936,019

Art Unit: 1646

Page 4

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen O'Hara whose telephone number is (703) 308-3312. The examiner can normally be reached on m-f.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Elea B. O. Hara